

In re Application of:
Hall et al.
Application No.: 09/218,913
Filed: December 22, 1998
Page 2

PATENT
Attorney Docket No.: AERO1120

Amendment to the Claims

Claims 11-13 and 15 were previously withdrawn.

The listing of claims will replace all prior versions, and listings of claims in the application.

Listing of Claims:

1. (Previously presented) A method for accelerating the rate of mucociliary clearance in a subject with chronic obstructive lung disease (COLD) comprising administering to the subject a therapeutically effective mucociliary clearance stimulatory amount of a composition comprising a substantially purified human serine protease inhibitor protein containing at least one Kunitz-like domain.
2. (Original) The method according to claim 1, wherein said composition is administered to the lung airways.
3. (Original) The method according to claim 1, wherein said composition is administered directly by aerosolization.
4. (Original) The method according to claim 1, wherein said composition is administered directly as an aerosol suspension into the mammal's respiratory tract.
5. (Original) The method according to claim 4, wherein said aerosol suspension includes respirable particles ranging in size from about 1 to about 10 microns.
6. (Original) The method according to claim 4, wherein said aerosol suspension includes respirable particles ranging in size from 1 to about 5 microns.
7. (Original) The method according to claim 4, wherein said aerosol suspension is delivered to said subject by a pressure driven nebulizer.
8. (Original) The method according to claim 4, wherein said aerosol suspension is delivered to said subject by an ultrasonic nebulizer.

9. (Original) The method according to claim 4, wherein said aerosol suspension is delivered to said subject by a non-toxic propellant.
10. (Previously presented) The method according to claim 1, wherein said carrier is a member selected from the group consisting of a buffered solution, an isotonic saline, normal saline, and combinations thereof.
11. (Withdrawn) The method according to claim 1 wherein the Kunitz-type serine protease inhibitor is aprotinin.
12. (Withdrawn) The method according to claim 1, wherein the Kunitz-type serine protease inhibitor comprises the amino acid sequence: (SEQ ID NO.: 49).
13. (Withdrawn) The method according to claim 1, wherein the Kunitz-type serine protease inhibitor comprises the amino acid sequence: (SEQ ID NO.: 2), (SEQ ID NO.: 45), (SEQ ID NO.: 47), (SEQ ID NO.: 70), or (SEQ ID NO.: 71).
14. (Previously presented) The method according to claim 1, wherein the substantially purified human serine protease inhibitor protein containing at least one Kunitz-like domain comprises the amino acid sequence: (SEQ ID NO.: 4), (SEQ ID NO.: 5), (SEQ ID NO.: 6), (SEQ ID NO.: 7), (SEQ ID NO.: 3), (SEQ ID NO.: 50), (SEQ ID NO.: 1), OR (SEQ ID NO.: 52).
15. (Withdrawn) The method according to claim 1, wherein the Kunitz-type serine protease inhibitor comprises the amino acid sequence: (SEQ ID NO.: 8).
16. (Previously presented) The method according to claims 12, 13, 14 or 15, wherein the substantially purified human serine protease inhibitor protein containing at least one Kunitz-like domain is glycosylated.
17. (Previously presented) The method according to claims 12, 13, 14 or 15, wherein the substantially purified human serine protease inhibitor protein containing at least one Kunitz-like domain contains at least one intra-chain cysteine-cysteine disulfide bond.

In re Application of:

Hall et al.

Application No.: 09/218,913

Filed: December 22, 1998

Page 4

PATENT

Attorney Docket No.: AERO1120

18. (Previously presented) The method according to claims 12, 13, 14 or 15, wherein the substantially purified human serine protease inhibitor protein containing at least one Kunitz-like domain contains at least one intra-chain cysteine-cysteine disulfide bond selected from the cysteine-cysteine paired groups consisting of CYS11-CYS61, CYS20-CYS44, CYS36-CYS57, CYS106-CYS156, CYS115-CYS139, and CYS131-CYS152, wherein the cysteine residues are numbered according to the amino acid sequences of SEQ ID NO.: 52.

19. (Previously presented) A method for accelerating the rate of mucociliary clearance in a subject having a chronic obstructive lung disease (COLD) comprising administering to the subject a therapeutically effective mucociliary clearance stimulatory amount of a composition comprising a substantially purified human serine protease inhibitor protein containing at least one Kunitz-like domain and a physiologically acceptable carrier, wherein the inhibitor is selected from a group consisting of: SEQ ID NO.: 49; SEQ ID NO.: 2; SEQ ID NO.: 45; SEQ ID NO.: 47; SEQ ID NO.: 71; SEQ ID NO.: 70; SEQ ID NO.: 4; SEQ ID NO.: 5; SEQ ID NO.: 6; SEQ ID NO.: 7; SEQ ID NO.: 3; SEQ ID NO.: 50; SEQ ID NO.: 1; SEQ ID NO.: 52; and SEQ ID NO.: 8.

20. (Previously presented) The method according to claim 19, wherein the composition is administered to the lung airways.

21. (Previously presented) The method according to claim 19, wherein the composition is administered directly by aerosolization.

22. (Previously presented) The method according to claim 19, wherein the composition is administered directly as an aerosol suspension into the mammal's respiratory tract.

23. (Previously presented) The method according to claim 22, wherein the said aerosol suspension includes respirable particles ranging in size from about 1 to about 11 microns.

24. (Previously presented) The method according to claim 22, wherein the said aerosol suspension includes respirable particles ranging in size from about 1 to about 5 microns.

25. (Previously presented) The method according to claim 22, wherein the said aerosol suspension is delivered to said subject by a pressure driven nebulizer.

In re Application of:

Hall et al.

Application No.: 09/218,913

Filed: December 22, 1998

Page 5

PATENT

Attorney Docket No.: AERO1120

26. (Previously presented) The method according to claim 22, wherein the said aerosol suspension is delivered to said subject by an ultrasonic nebulizer.

27. (Previously presented) The method according to claim 22, wherein the said aerosol suspension is delivered to said subject by a non-toxic propellant.

28. (Previously presented) The method according to claim 19, wherein said carrier is a member of selected from the group consisting of a physiologically buffered solution, an isotonic saline, normal saline, and combination thereof.

29. (Previously presented) The method according to claim 19, wherein the substantially purified human serine protease inhibitor protein containing at least one Kunitz-like is glycosylated.

30. (Previously presented) The method of claims 1 or 19, wherein the chronic obstructive lung disease is cystic fibrosis.